

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on August 3, 2006. A petition for a one month extension of time is submitted herewith. The Director is authorized to charge \$120.00 for the petition for extension of time and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-593 on the account statement.

Claims 65-76 and 78-93 are pending in this application. Claims 1-64 and 77 were previously canceled. In the Office Action, Claims 65-76 and 78-93 are rejected under 35 U.S.C. §102. In response Claim 90 has been amended, and Claims 83-85 have been canceled. This amendment does not add new matter. In view of the amendments and/or for the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 65-76 and 78-93 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,643,623 to Schmitz et al. ("*Schmitz*"). Applicants respectfully disagree with and traverse this rejection for at least the reasons set forth below.

Applicants have amended independent Claim 90 to recite, in part, a primary composition for oral use. The amendment is supported in the specification, for example, at page 2, lines 9-19. Independent Claims 65 and 90 recite, in part, a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. In contrast, Applicants respectfully submit that the cited reference fails to disclose or suggest each and every element of the present claims.

Applicants submit an Affidavit under 37 C.F.R. §1.132 ("*Affidavit*" attached hereto as Exhibit A) that demonstrates the deficiencies of the prior art with respect to the present claims. As supported by the *Affidavit*, *Schmitz* fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound as required, in part, by the present claims. Instead, *Schmitz* is directed to a health food product containing a first component in the form of a discrete portion within a second component. The first component includes antioxidants in a lipid containing core of the food product. As a result, because *Schmitz* teaches putting antioxidants a

lipid-based core, the antioxidants in *Schmitz's* composition are in an internalization and heterogeneous form, which is distinguishable from the homogenous mixture of the LBC and whey protein in accordance with the present claims.

As supported by the *Affidavit*, *Schmitz's* product fails to achieve increasing the bioavailability of the LBC with whey protein in accordance with the present invention. *Schmitz* specifies that the antioxidants are preferably localized in a lipid-based carrier within the food product. See, *Schmitz*, column 3, lines 19-22. In contrast to *Schmitz*, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For example, rather than being in a lipid-based carrier as in *Schmitz*, the LBC of the present claims is distributed uniformly through a whey protein thereby providing the unexpected and important benefits of increased bioavailability of the LBC. Applicants respectfully submit that one skilled in the art would find that *Schmitz* entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by whey protein as a matrix.

In sum, the cited reference fails to provide or recognize a solution to the present technical problem of enhancing the bioavailability of the LBCs as Applicants' invention has done. *Schmitz* only teaches ways to protect compounds from oxidation via internalization or containing within a lipid core and not increase the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins as required, in part, by the present claims. While *Schmitz* may have sought to provide bioactive compounds for health-related purposes, it does not recognize or even achieve the bioavailability-enhancing function of whey protein that can be utilized by mixing the whey protein with an LBC. For at least the reasons discussed above, *Schmitz* does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious.

Accordingly, Applicants respectfully request that the rejection of Claims 65-76 and 78-93 under 35 U.S.C. §102 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

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Dated: November 22, 2006

EXHIBIT A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): K. Bortlik et al.
Appl. No.: 10/057,660
Conf. No.: 4348
Filed: January 25, 2002
Title: PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE
COMPOUND
Art Unit: 1651
Examiner: R.A. David
Docket No.: 112701-593

AFFIDAVIT UNDER 37 C.F.R. § 1.132

Sir:

I hereby state as follows:

1. My experience and qualifications are as follows:

*- Diploma in Biology and Ph.D. in Plant
Physiology (University of Zurich, Switzerland)
- Since 1995 at Nestle Research Center with
former projects on colour stabilisation in food;
extraction of plant constituents. Current projects
functionalisation of bioactives for improved delivery.*

2. I am the named inventor of the above-identified patent application and am therefore familiar with the inventions disclosed therein.

3. I have reviewed the outstanding Office Action dated August 3, 2006 pending against the above-identified patent application. In addition to considering the outstanding Office Action, I have reviewed the reference cited therein as well as the pending claims. I believe that the anticipation rejection of Claims 65-76 and 78-93 under 35 U.S.C. §102(b) based on U.S. Patent No. 5,643,623 to Schmitz et al. ("Schmitz") is based on a misunderstanding of the reference and the pending claims. The basis for my opinion is set forth below.

4. The present invention is directed, in part, to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound ("LBC") and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. For example, a process for the preparation of the oral primary composition comprises associating the whey protein with the lipophilic bioactive compound under conditions sufficient to form the composition a mixture. The composition may be formed by dissolving the whey protein in water to form a first solution, dissolving the lipophilic bioactive compound in a solvent to form a second solution, combining the two solutions, and evaporating the solvent to form the composition as a dispersion. Alternatively, the composition may be formed by mixing the lipophilic bioactive compound with a solvent to form a first mixture, mixing the first mixture with the whey protein in the form of a powder to form a second mixture and evaporating the solvent from the second mixture to produce the composition as a dry powder.

5. The present invention relates to increasing the bioavailability of a lipophilic bioactive compound by the novel feature of associating the lipophilic bioactive compound with a whey protein to form a mixture. By mixing an LBC with a whey protein, the present invention makes available to a subject an LBC-containing composition with better bioavailability compared to consuming an LBC alone. As summarized in Example 1 of the present specification, administration of the claimed composition -- formed by mixing a lipophilic bioactive compound, such as lycopene, with a whey protein in a mixture form -- has shown that the composition's LBC bioavailability is comparable to that of tomato puree or paste, which is known to have the best bioavailability of lycopene.

6. As one having ordinary skill, I believe that *Schmitz* does not disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. *Schmitz* teaches a health food product containing a first component in the form of a discrete portion within a second component. The first component includes antioxidants selected from carotenoids, vitamins C and E, and curcumin. *Schmitz* teaches internalization and integration of the above

nutrients within a lipid-containing core of the food product. Because *Schmitz* teaches putting antioxidants in a lipid-based core, the antioxidants in *Schmitz's* composition are in an internalization and heterogeneous form. In contrast, the composition of the present invention is a homogenous mixture of the LBC and whey protein.

7. As one having ordinary skill, I believe that *Schmitz's* product does not achieve enhancing bioavailability of the LBC with whey protein in accordance with the present invention. *Schmitz's* teaches protecting compounds from oxidation via internalization or containing within a lipid core. *Schmitz* specifies that the antioxidants are localized in a lipid-based carrier within the food product. *Schmitz* does not teach increasing the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins in accordance with the present invention. In contrast to the discrete internalization form in a lipid-based carrier taught by *Schmitz*, the LBC is distributed uniformly throughout the whey protein in the present invention, thereby providing the unexpected and important benefit of increased bioavailability of the LBC. The compound of *Schmitz* would not result in increased bioavailability of the LBC because it is at least partially surrounded in the lipid-based core. As a result, I believe that *Schmitz's* product does not inherently achieve the same function as the claimed invention.

8. For all the foregoing reasons, as one having ordinary skill in the art, it is my opinion that *Schmitz* fails to teach or suggest the claimed primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. I believe that *Schmitz* teaches that the antioxidants are preferably localized in a lipid-based carrier within the food product, which does not disclose, teach or suggest that the lipid core may be eliminated and replaced with whey protein as a mixture. I also believe that the function and benefit of the present mixture composition could not have been inherent in the at least partially surrounded *Schmitz* composition because of their significant differences in form and functional properties.

Appl. No. 10/057,660

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that willful false statements may jeopardize the validity of this patent and any patent issuing therefrom.

Date: 13/11/06

K. Bortlik

Print Name Karlheinz Bortlik